IN THE UNITED STATES COURT OF APPEALS
FOR THE SEVENTH CIRCUIT

ELI LILLY AND COMPANY AND LILLY USA, LLC

Plaintiffs-Appellants,

v.

XAVIER BECERRA, ET AL.,

Defendants-Appellees.

On Appeal from the United States District Court
for the Southern District of Indiana, No. 21-81 (Barker, J.).

COURT-ORDERED JURISDICTIONAL MEMORANDUM FOR THE DEFENDANTS-APPELLEES

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BACKGROUND

This appeal arises from a suit brought by drug manufacturers who participate in Medicare against the U.S. Department of Health and Human Services (HHS) and other federal defendants. By statute, drug manufacturers who wish for their products to be covered by Medicare Part B and Medicaid must participate in the 340B Drug Price Program. 42 U.S.C. § 256b. Under the 340B program, participating manufacturers "sell their outpatient drugs at a heavily discounted price" to covered entities, such as "not-for-profit hospitals, community centers, and other federally funded clinics serving low-income patients." Order at 4, Dkt. 144, *Eli Lilly Co. v. U.S. Department of Health and Human Servs.*, No. 21-81 (S.D. Ind. Oct. 29, 2021) (hereinafter Order). Many of those covered entities do not have their own in-house pharmacies to dispense drugs to patients—instead, they contract with outside pharmacies to do so. 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996). For the last 25 years, HHS has explained that drug manufacturers who participate in the 340B program must provide drugs at discounted rates regardless of whether a particular covered entity dispenses those drugs through an in-house pharmacy or through an outside contract pharmacy. *Id.* at 43449-50.

In 2020, plaintiff Eli Lilly informed HHS that "with certain caveats it would no longer offer 340B pricing throughout contract pharmacy arrangements for one of its drugs." Order at 11. Eli Lilly later expanded this practice to all of its products. *Id.* at 12. In December 2020, HHS's General Counsel issued an advisory opinion on this issue, stating that the discounted rates of the 340B program generally apply to covered entities who contract with outside pharmacies. *Id.* at 13-14. In May 2021, a subagency of HHS, the Health Resources and Services Administration, sent Eli Lilly a letter notifying the company that its "actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* at 16. The letter also stated that "[c]ontinued failure to provide the 340B price to covered entities" that contract with outside pharmacies could result in civil monetary penalties. *Id.*

Plaintiffs then sued in district court for a declaratory judgment and injunctive relief, and they challenged the advisory opinion, the enforcement letter, and other matters. Second Amended Compl. at 99-100, Dkt. 103, *Eli Lilly Co. v. U.S. Department of Health and Human Servs.*, No. 21-81 (S.D. Ind. May 27, 2021). The district court issued a summary judgment opinion addressed only the challenges to the advisory opinion and the enforcement letter.

The district court vacated the advisory opinion as arbitrary and capricious but concluded that no remand was necessary because HHS had already withdrawn the letter. Order at 34. The district court also rejected several of plaintiffs' challenges to the enforcement letter. The court held that the letter was not subject to the notice-and-comment requirements of 5 U.S.C. § 553, and therefore did not violate those requirements. *Id.* at 36-37. The court further held that the enforcement letter did not exceed the agency's statutory authority, but instead appropriately construed the 340B statute to prohibit "[Eli] Lilly's policy under which it delivers drugs to only one location per covered entity and otherwise charges covered entities prices high above the ceiling price for covered outpatient drugs." *Id.* at 49-50. The court also held that this statutory interpretation was neither a taking of private property, nor an unconstitutional condition. *Id.* at 50-52. The court nevertheless vacated and remanded the enforcement letter as arbitrary and capricious, concluding that the letter failed to adequately explain the agency's "change in position regarding its authority to enforce potential violations of the 340B statute." *Id.* at 52.

In conjunction with its opinion, the district court granted partial final judgment under Federal Rule of Civil Procedure 54(b). Partial Final

Judgment, Dkt. 145, *Eli Lilly Co. v. U.S. Department of Health and Human Servs.*, No. 21-81 (S.D. Ind. Oct. 29, 2021). The judgment reads:

> The Court, having on this day granted summary judgment in favor of Plaintiffs on Counts III and XII and in favor of Defendants on Counts X, XI, and XIII, finds, pursuant to Federal Rule of Civil Procedure 54(b), that there is no just reason for delay. Accordingly, partial final judgment is hereby entered in favor of Defendants and against Plaintiffs on Counts X, XI, and XIII and in favor of Plaintiffs and against Defendants on Counts III and XII. HHS's General Counsel's December 30, 2020 Advisory Opinion and HRSA's May 17, 2021 Enforcement Letter are hereby SET ASIDE and VACATED and HRSA's May 17, 2021 Enforcement Letter is REMANDED to the agency.

Plaintiffs filed a notice of appeal, and on November 16, 2021, this Court ordered the parties to file a brief memorandum "stating why this appeal should not be dismissed for lack of jurisdiction, or sent back to the district court as was done in" *Philadelphia Indemnity Ins. Co. v. The Chicago Trust Co.*, 930 F.3d 910, 912 (7th Cir. 2019) and *Greenhill v. Vartanian*, 917 F.3d 984 (7th Cir. 2019).

DISCUSSION

Under this Court's precedents, it may be appropriate to remand this appeal for the limited purpose of allowing the district court to clarify its judgment to specifically declare the parties' rights. Under Federal Rule of Civil Procedure 58, the district court's judgment "must declare specifically and separately the respective rights of the parties." *INTL FCStone*

Financial Inc. v. Jacobson, 950 F.3d 491, 502 (7th Cir. 2020) (quoting *Calumet River Fleeting, Inc. v. International Union of Operating Engineers, Local 150, AFL-CIO*, 824 F.3d 645, 651 (7th Cir. 2016)). If the judgment does not do so, the Court may still be able to exercise jurisdiction over the appeal if "the practicalities weigh heavily toward a common sense conclusion that the district court intended to enter a final judgment" and it is "sufficiently plain both what the court declared and that the district court was finished with the case." *Calumet River Fleeting*, 824 F.3d at 651 (quotation marks omitted).

Here, the judgment makes clear that the district court intended to enter a partial final judgment under Federal Rule of Civil Procedure 54(b) and to allow for an appeal on the claims it had adjudicated. The judgment is also clear as to the remedies ordered by the court—vacatur of both the advisory opinion and the enforcement letter, and a remand to the agency on the enforcement letter—but it does not separately declare the respective rights of the parties. Instead, the judgment decides certain claims by referring to counts in the plaintiffs' complaint. This Court, however, has held that "[j]udgments must not recite the pleadings and other papers that led to the decision." *Hyland v. Liberty Mutual Fire Ins. Co.*, 885 F.3d 482, 483 (7th Cir. 2018).

In recent cases, this Court has remanded the appeal to the district court for the limited purpose of modifying the judgment to address similar concerns. *See Philadelphia Indemnity Ins. Co. v. Chicago Trust Co.*, 930 F.3d 910, 912 (7th Cir. 2019) ("We remanded with instructions to enter a new judgment" and "[t]he district judge complied"); *Greenhill v. Vartanian*, 917 F.3d 984, 987 (7th Cir. 2019) (the Court "remand[ed] the case with instructions to enter a proper declaratory judgment" and "[t]he district court promptly complied"). The Court could appropriately order such a remand here, whereupon the district court could enter a judgment that declares the parties' rights consistent with its merits opinion. In other words, the district court's judgment could declare that (1) the advisory opinion is arbitrary and capricious under 5 U.S.C. § 706; (2) the enforcement letter does not violate the notice-and-comment requirements of 5 U.S.C. § 553; (3) the enforcement letter does not exceed statutory authority under 5 U.S.C. § 706; (4) contrary to plaintiffs' assertions, the government has "authority to require Lilly to offer or give 340B discounts to contract pharmacies or on purchases made by contract pharmacies,"* (5) the enforcement letter is not a taking under the Constitution's Takings

* Second Amended Compl. at 100, Dkt. 103, *Eli Lilly Co. v. U.S. Department of Health and Human Servs.*, No. 21-81 (S.D. Ind. May 27, 2021).

Clause; (6) the enforcement letter is not an unconstitutional condition on the receipt of benefits; and (7) the enforcement letter is arbitrary and capricious under 5 U.S.C. § 706.

Respectfully submitted,

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[†] The Acting Assistant Attorney General is recused in this matter.

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a) (5) and (6) because it has been prepared in 14-point Georgia, a proportionally spaced font. I further certify that it complies with the word limits of Fed. R. App. P. 27(d)(2) because it contains 1,369 words by the count of Microsoft Word 2016.

/s/ Daniel Aguilar
Daniel Aguilar